



***Reliance Orthodontic Products, Inc.***

Toll Free 1-800-323-4348 • Phone 630-773-4009 • Fax 630-250-7704  
PO Box 678 • Itasca, IL • 60143 • U.S.A.

K083051

FEB 20 2009

**Section 5.0**

**510 (k) Summary**

Note: This summary is provided in accordance with 21CFR807.92 (c).

510 (k) Owners Name: Reliance Orthodontic Products, Inc.  
Paul Gange, President

Address: 1540 West Thorndale Avenue  
Itasca, IL 60143 USA

Phone Number: 630-773-4009  
Fax Number: 630-250-7704

Contact Person: Paula Wendland, Regulatory Affairs Manager (Preparer)

Date 510 (k) Summary was Prepared: October 10, 2008

**Medical Device Name:**

- Trade name – Flowtain™ and Flowtain™ LV
- Common name – Flowable Light Cure Orthodontic Adhesive
- Classification name – Bracket Adhesive Resin and Tooth Conditioner  
(21CFR872.3750, Product Code DYH, Class II Device)

**LEGALLY MARKETING DEVICE TO WHICH EQUIVALENCE IS CLAIMED  
(PREDICATE DEVICE) [807.92(a) (3)]:**

- 3M Unitek Transbond™ Supreme LV
- Bisco Inc. TESCERAFLO™



*Reliance Orthodontic Products, Inc.*

Toll Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704  
PO Box 678 · Itasca, IL · 60143 · U.S.A.

**5.1 DESCRIPTION OF THE APPLICANTS DEVICE:**

Flowtain™ is a light-cure orthodontic adhesive with a low modulus of elasticity that is flowable. This low modulus of elasticity makes it ideal for bonding lingual retainers, splinting materials and for indirect bonding of brackets. Thixotropic design properties of Flowtain™ also make it highly polishable which allows it to be used for comfortable archwire stops and as an aid for retention of a thermo-plastic aligner.

Flowtain™ LV is a low viscosity version of the Flowtain™ product used primarily for indirect bonding of brackets.

Both are available in push syringe or tips for preferences in dispensing.

**5.2 INTENDED USE AND POPULATION:**

Flowtain™ is a flowable, light-cure orthodontic adhesive intended to be used within an orthodontic, dental or pediatric dental office for the bonding of lingual retainers and splinting materials, creation of archwire stops and indirect bonding of orthodontic brackets. Flowtain™ can also be used for the retention of thermo-plastic aligners.

Flowtain™ LV is a lower viscosity, flowable light cure orthodontic adhesive intended to be used for indirect bonding of orthodontic brackets.

**5.3 PREDICATE DEVICE:**

3M Unitek Transbond™ Supreme LV, 510(k) submission (K073697) dated 02/15/2008 for intended use.

Flowtain™ and Flowtain™ LV are similar in composition as Bisco Inc. TESCERAFLO™, 510(k) submission (K030951) for safety and performance.



***Reliance Orthodontic Products, Inc.***

Toll Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704  
PO Box 678 · Itasca, IL · 60143 · U.S.A.

**5.4 TECHNOLOGICAL AND PERFORMANCE CHARACTERISTICS:**

Performance Characteristics of Flowtain™ versus Transbond™ Supreme LV:

<b>Property</b>	<b>Flowtain</b>	<b>Transbond Supreme LV</b>
<b>Intended Use</b>	<b>Flowable Light Cure adhesive for bonding lingual retainers and indirect bonding of orthodontic brackets</b>	<b>Flowable Light Cure Adhesive for indirect bonding of orthodontic brackets and bonding to enamel surfaces.</b>
<b>Mechanical / Physical Properties</b>	<b>Single paste in a hand-held delivery system.</b>  <b>Flowable Composite</b>	<b>Single paste in a hand-held delivery mechanism.</b>  <b>Flowable Composite</b>

Performance Characteristics of Flowtain™ and Flowtain™ LV versus TESCERAFLO™:

<b>Property</b>	<b>Flowtain™ and Flowtain™ LV</b>	<b>TESCERAFLO™</b>
<b>Intended Use</b>	<b>Flowable Light Cure adhesive for direct and indirect bonding</b>	<b>Flowable Light Cure adhesive for direct or indirect restorations</b>
<b>Chemical Composition</b>	<b>Ethoxylated Bisphenol A Dimethacrylate Triethyleneglycol Dimethacrylate Glass Filler</b>	<b>Ethoxylated Bisphenol A Dimethacrylate Triethyleneglycol Dimethacrylate Glass Filler</b>

**5.5 Summary:**

Flowtain™ and Flowtain LV were tested against Transbond™ Supreme LV using in-vivo performance test method for shear bond strength. Testing was conducted using indirect bonding procedure in replicates of 5 for Flowtain™, Flowtain™ LV and Transbond™ Supreme LV, the predicate device. Testing resulted in similar performance between the two adhesives.

Flowtain™ has been tested and proven to be non-toxic.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 20 2009

Ms. Paula Wendland  
Regulatory Affairs Manager  
Reliance Orthodontic Products, Incorporated  
1540 West Thorndale Avenue  
Itasca, Illinois 60143

Re: K083051

Trade/Device Name: Flowtain™ and Flowtain™ LV  
Regulation Number: 21CFR 872.3750  
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner  
Regulatory Class: II  
Product Code: DYH, EBF  
Dated: February 13, 2009  
Received: February 17, 2009

Dear Ms. Wendland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Ginette Y. Michaud, M.D.

Acting Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



*Reliance Orthodontic Products, Inc.*

Toll Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704  
PO Box 678 · Itasca, IL · 60143 · U.S.A.

## SECTION 6.0 INDICATIONS FOR USE STATEMENT

### Indications for Use

510 (k) Number (if known): \_\_\_\_\_

Device Name: \_\_\_\_\_ Flowtain™ and Flowtain™ LV \_\_\_\_\_

#### Indications for Use:

Flowtain™ is a flowable, light-cure orthodontic adhesive intended to be used within an orthodontic, dental or pediatric dental office for the bonding of lingual retainers and splinting materials, creation of archwire stops and indirect bonding of orthodontic brackets. Flowtain™ can also be used for the retention of thermo-plastic aligners.

Flowtain™ LV is a lower viscosity, flowable light cure orthodontic adhesive intended to be used for indirect bonding of orthodontic brackets.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:   168305